

REMARKS/ARGUMENTS

Applicants have studied the Office Action dated May 7, 2009, and have made the above amendments and the following remarks and submit that all pending claims 1 to 10, 17 to 18, and 21 to 32 of the present application are in condition for allowance. Claims 1, 17, 21, 22 and 32 have been amended. Reconsideration and allowance of the pending claims in view of the above amendments and the following remarks is respectfully requested.

In the final Office Action, the Examiner maintained the following:

- (1) rejected claims 1, 2, 4, 17, 18, 21-23, 25 and 32 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,620,452 to *Yoon*,¹
- (2) rejected claims 3, 7, 24 and 28 under 35 U.S.C. § 103(a) as being unpatentable over *Yoon* in view of U.S. Patent No. 5,222,961 to *Nakao et al.* (hereinafter "Nakao"); and
- (3) rejected claims 5, 6, 8-10, 26, 27 and 29-31 under 35 U.S.C. § 103(a) as being unpatentable over *Yoon* in view of *Nakao*, and in further view of U.S. Patent No. 4,719,917 to *Barrows et al.* (hereinafter "Barrows").

(1) Rejection under 35 U.S.C. § 102(b)

As noted above, the Examiner maintained the rejection of claims 1, 2, 4, 17, 18, 21-23, 25, and 32 under 35 U.S.C. § 102(b) as being anticipated by *Yoon* despite the fact that *Yoon* does not describe a surgical clip having a bridge that connects a first arm and a second arm to form a **substantially static** U-shaped structure and also does not describe the shape being retained prior to, throughout and subsequent to application of the clip, each of which are required elements of each independent claim (i.e., claims 1, 17, 21, 22 and 32). Accordingly, *Yoon* does not anticipate each and every element of the presently claimed invention and, therefore, the anticipation rejection should be withdrawn.

¹ It is noted that item 1 on page 1 of the Final Office action seems to be an erroneous carry-over from the October 22, 2008 non-final Office action. Accordingly, Applicants have disregarded this item in the instant amendment.

In response to the Non-Final Office Action dated October 22, 2008, Applicants filed a Response on January 22, 2009 (hereinafter "*Response*"), in which Applicants provided a comprehensive argument that *Yoon* does not describe the substantially static U-shaped structure as it is defined and referred to in the specification and in the claims of the present application. Nevertheless, the Examiner has concluded that the clip described in *Yoon* is "fully capable of retaining its substantially U-shaped configuration prior to, throughout, and subsequent to application." See Office Action, page 2.

I. THE PRESENT INVENTION

As was set forth in the Response and throughout the present application, Applicants' invention concerns a surgical clip inserted by a clip applier after the clip applier jaws grasp and puncture the invaginated fundus. See, e.g., pages 19-21 of the application as originally filed; *Response*, pages 3-4. The tissue is plicated and the retainer arms are caused to slide over the tissue for a distance. *Id.* Then, *only* the retainer portion of the surgical clip is plastically deformed to affix the clip to the fundus. *Id.* The claims, as written, provide that a property of the connecting bridge is that its stiffness retains the two parallel arms in the same initial U-shaped form **prior to, throughout, and subsequent to** application. *Id.*, page 23. The bridge secures the arm elements in a **substantially static** position throughout the entire application, an orientation that keeps pressure upon the tissue therebetween. It is only the deformable retainer at the end of one or both of the arms that is/are designed to deform plastically. Independent claims 1, 17, 21, 22 and 32 have been amended in order to further clarify that the bridge does not just retain a U-shaped structure prior to, throughout, and subsequent to application, but it also retains substantially the same initial U-shaped structure prior to, throughout, and subsequent to application such that the shape and diameter of the U-shape does not change in any relevant way. This amendment has been made only as a clarification in response to the Examiner's rejection of the claims under 35 U.S.C. § 102(b) and, therefore, no new matter is being introduced nor are any equivalents being surrendered.

II. THE DEVICE IN YOON

A single embodiment of the clip in *Yoon* could be said to resemble a U-shaped structure. But that is where the similarity ends. As shown in FIG. 10, staples 40 mounted on the upper and lower arms 16 and 18 are in opposition to corresponding apertures 36 formed in the lower and upper arms 18 and 16. *Yoon*, col. 4, lines 42-46. These corresponding areas 36 and 40 show that the upper and lower arms are **designed to meet each other or at least approach each other during application of the clip**. If the arms were moved to where staples 40 were at least 3.14 times the distance between the arms when the arms are substantially parallel (as is recited in claims 1, 17 and 22 of the present application), the bridge section of *Yoon* would no longer resemble a U-shape, but would be a V-shape, as is shown in all of the other illustrated embodiments of *Yoon*. If the clip in *Yoon* must be manipulated to meet this recitation of the claims of the present application, then, by definition, it cannot also be “a **substantially static** U-shaped structure,” as the claims of the present application also recite. In addition, the embodiment shown in FIG. 10 of *Yoon* is described as having “plastically shaped or deformed legs” (*Yoon*, col. 4, lines 49-59) – a configuration that is in direct opposition to the invention, which has “a first arm...a second arm...and a bridge connecting said first and second arms to form a **substantially static** U-shaped structure retaining the shape prior to, throughout, and subsequent to application” as recited in the independent claims of the present application.

Furthermore, on pages 2 and 4 of the Office Action, the Examiner notes that “the amount of separation between the two arms merely depends on the amount of force used to press the arms together” and “the shape of the U-shaped structure is merely dependent upon the manipulation of the clip.” Thus, the Examiner acknowledges that the clip in *Yoon* is **not static**. The arm separation is dependent upon the force used to press the arms together and the clip must be **manipulated** in order to form a U-shaped structure. Therefore, the bridge of the clip in *Yoon* does not connect first and second arms to form a **substantially static** U-shaped structure. Based on the Examiner's interpretation alone, it is clear that *Yoon* discloses a clip **that only functions if the arms are moved together during normal operation (i.e., they are deformable, non-static) so that the apertures 36 and staple 40 intersect with each other**. In stark

contrast, the arms of the clip of the present invention remain “**substantially static**” prior to, throughout, and subsequent to application. Also, the clip in *Yoon* would not function to allow tissue in between the arms if the staples were “at least at least 3.14 times the distance between the arms when the arms are substantially parallel.”

Despite having acknowledged the above non-static characteristics of the clip in *Yoon*, the Examiner concluded that the clip “merely has to have the capability of being applied to a tissue while maintaining the original 'U-shaped structure' of the undeployed clip” and identified FIG. 13 as depicting the clip being attached to tissue while maintaining the same U-shaped structure shown in the undeployed clip in FIG. 12. See Office Action, page 4. Applicants respectfully disagree with the Examiner’s conclusion as the series of steps for applying the clip to a tissue does not end with what is shown in FIG. 13. FIG. 13 illustrates only one intermediate step in the overall application of the clip. As described in *Yoon*, FIGS. 13 through 15 are side views illustrating use of the clip. *Yoon*, col. 2, lines 64-65; col. 5, lines 27-28. In FIG. 13, tissue is positioned between arms 16 and 18 of the clip with staple legs 50 retracted. The clip 10 is compressed thereby causing the tissue penetrating legs 50 to be driven through openings in the arms and into the tissue. *Id.*, at col. 5, lines 27-47. In FIG. 14, **further compression** is what causes the cross-members 48 to abut respective outer surfaces of arms 16 and 18 as the arms are moved towards one another against the tissue. *Id.* As is clearly shown in FIG. 14, the bridge 14 is **not static** and does not maintain the same shape shown in FIGS. 12 and 13 as the arms are compressed towards one another (i.e., it is not static “throughout” application). In FIG. 15, once the arms 16 and 18 have been compressed together far enough such that they are separated by a distance somewhat less than the length the tissue penetrating legs 50, the legs 50 are able to pass through apertures 36 in the opposed arm and, then, are in a state to be bent around the other side to lock the arms together without distal ends of the arms being coupled. *Id.* As is clearly shown in FIG. 15, although the bridge appears to have returned to a U-shape, the diameter of the U-shape has significantly decreased from the diameter shown in FIG. 12 so that the arms can be locked. Without the ability to change and deform the shape and diameter of bridge 14 in a non-static way, the clip in *Yoon* could not be attached to the tissue and function as intended.

The Examiner cites 35 U.S.C. § 102(b) and a proper rejection requires that a single reference teach (i.e., identically describe) each and every element of the rejected claims as being anticipated by *Yoon*.² Because the elements in independent claims 1, 17, 21, 22, and 32 of the instant application are not taught or disclosed by *Yoon*, the device in *Yoon* does not anticipate the present invention. The dependent claims are believed to be patentable as well because they all are ultimately dependent on either claim 1, 17, 21, 22, or 32. Accordingly, the present invention distinguishes over *Yoon* for at least this reason. Applicants respectfully submit that the Examiner's rejection under 35 U.S.C. § 102(b) has been overcome.

(2) Rejection under 35 U.S.C. § 103(a) *Yoon* in view of *Nakao*

As noted above, the Examiner rejected claims 3, 7, 24, and 28 under 35 U.S.C. § 103(a) as being unpatentable over *Yoon* in view of *Nakao et al.* (U.S. 5,222,961).

The Examiner attempts to combine *Yoon* with *Nakao* to sustain an obviousness rejection. The arguments set forth above in section "(1) Rejection under 35 U.S.C. §102(b)" are incorporated herein. Claims 3 and 7 depend directly from independent claim 1 and claims 24 and 28 depend from independent claim 22. Independent claims 1 and 22 distinguish over *Yoon*. Since dependent claims contain all the limitations of the independent claims, claims 3, 7, 24, and 28 distinguish over *Yoon*, as well.

Accordingly, the Applicants respectfully submit that it is not necessary at this stage to address the *Nakao* reference as applied to claims 3, 7, 24, and 28. Nor is it necessary to address whether or not there is sufficient suggestion or motivation with a reasonable expectation of success for modifying the *Yoon* reference, as required by MPEP § 2143.

² See MPEP §2131; "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (emphasis added.) . . . "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

As such, Applicants respectfully request that the Examiner's rejection of claims 3, 7, 24, and 28 be withdrawn.

(3) Rejection under 35 U.S.C. §103(a) Yoon in view of Nakao and Barrows

As noted above, the Examiner rejected claims 5, 6, 8-10, 26, 27, and 29-31 under 35 U.S.C. § 103(a) as being unpatentable over *Yoon* in view of *Nakao*, and further in view of *Barrows* (U.S. 4,719,917).

The Examiner attempts to combine *Yoon* and *Nakao* with *Barrows* to sustain this obviousness rejection. The arguments set forth above in section "(1) Rejection under 35 U.S.C. §102(b)" are incorporated herein. Claims 5, 6, and 8-10 depend directly from independent claim 1 and claims 26, 27, and 29-31 depend directly from independent claim 22. Independent claims 1 and 22 distinguish over *Yoon*. Since dependent claims contain all the limitations of the independent claims, claims 5, 6, 8-10, 26, 27, and 29-31 distinguish over *Yoon*, as well.

Accordingly, the Applicants respectfully submit that it is not necessary at this stage to address the *Nakao* and *Barrows* references as applied to claims 3, 7, 24, and 28. Nor is it necessary to address whether or not there is sufficient suggestion or motivation with a reasonable expectation of success for modifying the *Yoon* reference, as required by MPEP § 2143. As such, the Applicants respectfully request that the Examiner's rejection of claims 5, 6, 8-10, 26, 27, and 29-31 be withdrawn.

CONCLUSION

Applicants acknowledge the continuing duty of candor and good faith to disclosure of information known to be material to the examination of this application. In accordance with 37 CFR §1.56, all such information is dutifully made of record. The foreseeable equivalents of any territory surrendered by amendment are limited to the territory taught by the information of record. No other territory afforded by the doctrine of equivalents is knowingly surrendered and everything else is unforeseeable at the time of this

amendment by the Applicants and their attorneys.

Applicants respectfully submit that all of the grounds for rejection stated in the Examiner's Office Action have been overcome, and that all claims in the application are allowable. No new matter has been added. It is believed that the application is now in condition for allowance, which allowance is respectfully requested.

It is believed that no fee is due with this Amendment. However, if any fees are due with respect to Sections 1.16 or 1.17, please charge to the deposit account of the undersigned firm, Acct. No. 503,836.

PLEASE CALL the undersigned if that would expedite the prosecution of this application.

Respectfully submitted,

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